

REMARKS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the amendments and remarks herewith, which place the application into condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-15, 19-24 and 29-32 are pending in this application. Claims 1-4, 8-11, 15, 19 and 29 have been amended; claims 30-32 have been added; and claims 16-18 have been cancelled. No new matter is added.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. §112. The amendments of and additions to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support is found throughout the specification and from the pending claims. Furthermore, it is explicitly stated that the herewith amendments should not give rise to any estoppel, as the herewith amendments are not narrowing amendments.

Formal Drawings

In response to the Draftperson's objection to Figure 1, attached please find a formal drawing replacement.

Claim Objections

Claim 29 was objected to for depending upon a non-elected claim. Claim 19 was objected to as being in improper form for a multiple dependent claim. These matters have been attended to by amendment.

II. THE REJECTIONS UNDER 35 U.S.C. §101 ARE OVERCOME

Claims 16-18 were rejected under 35 U.S.C. §101 as being improper process claims. These claims have been cancelled, obviating the rejection. Withdrawal is requested.

III. THE REJECTIONS UNDER 35 U.S.C. §112, 2ND PARAGRAPH, ARE OVERCOME

Claims 1-5, 8-11 and 15-18 were rejected under 35 U.S.C. §112, second paragraph as being indefinite. Claims 16-18 have been cancelled. It is believed that the amendments to the claims

overcome most of the Section 112, second paragraph issues. For example, claims 2, 3 and 8-11 have been amended to clarify the role of the "single nucleic acid molecule". It should be noted that the double constructs described on page 8, lines 15-16, and on page 23, lines 6-14 of the application can be used to simultaneously decrease the activity of GBSSI and BE.

The rejection of claims 16 and 17 based on the recitation of "enzymatic activity of GBSSI and BE", now recited in new claim 30, is traversed. The paragraph beginning on page 5, line 16 describes GBSSI as an enzyme which plays a role in synthesizing amylose starch. Plants containing less GBSSI (or which have reduced GBSSI activity) produce amylose-free or waxy starch. Likewise, the branching enzyme (BE) is described in the first paragraph on page 6 as an enzyme which catalyzes a transglycosylation reaction. Methods for measuring a decrease in enzymatic activity are cited on page 12 in the paragraph beginning on line 6. Inherent in such methods is a determination of enzymatic activity of GBSSI and BE.

Claim 30 clearly reads on the final product - a transgenic plant or plant cell. It is the final result of the enzymatic activity that is being measured by the method (i.e., amount of amylose in starch and/or degree of branching); therefore, it does not matter whether the assay used measures substrate binding or kinetics. The skilled artisan will be able to determine whether the claimed transgenic plant or plant cell have reduced enzymatic activity of GBSSI and/or BE.

Reconsideration and withdrawal of the Section 112, second paragraph, rejections is solicited.

IV. THE REJECTIONS UNDER 35 U.S.C. §112, 1ST PARAGRAPH, ARE OVERCOME

Claims 1-24 and 29 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking adequate written description. Claims 1-24 and 29 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. These rejections are traversed.

The Office Action alleges that the claims are drawn to a multitude of nucleic acid molecules which decrease the activity of GBSSI and BE enzymes without affecting the expression of the genes encoding them. The claims are drawn only to such plant cells in which the activity of both GBSSI and BE is decreased, wherein the term "activity", as defined on page 11, lines 18-22 of the specification, not only refers to the protein activity but also to the expression of the genes encoding the proteins. The claims do not relate to nucleic acids which individually or simultaneously decrease the activity of GBSSI and/or BE without affecting the expression of genes encoding them.

It was known in the art at the time of filing that various techniques such as antisense, cosuppression, ribozyme and *in vivo* mutagenesis technologies could be employed to decrease the level of gene expression. A description of these technologies with corresponding references can be found on pages 8-10 of the specification. In addition, the DNA sequence information required for carrying out antisense or cosuppression experiments was known in the art and is disclosed in the application (page 5, line 16 to page 6, line 27). Therefore, the skilled artisan is able to make plants with reduced activity of the GBSSI and BE protein based on the teachings of the specification.

In addition, the structural features of nucleic acid molecules that simultaneously inhibit the expression of both GBSSI and BE can be derived from page 8, second paragraph and page 23, lines 6-14 of the specification. Structural features of GBSSI or BE genes or enzymes can be derived from the specification, which refers to numerous known DNA and protein sequences of GBSSI and BE enzymes (page 5, line 16 to page 6, line 27 of the specification). Further, the person skilled in the art is able to identify further genes without undue experimentation by homology comparison (page 9, lines 17-23). Proteins having GBSSI or BE activity could thus be identified.

The Office Action also alleges that no guidance is provided for a multitude of fragments of BE or GBSSI genes encoding a multitude of BE or GBSSI protein fragments, or for the use of the gene fragments to produce plants with modified starch. The last paragraph on page 8 of the specification teaches antisense fragments; page 9, lines 13-15, teach that fragments can be used for cosuppression constructs. It was well-known in the art at the time of filing that full length sequences are not required for successfully conducting antisense and cosuppression experiments. It was known also known that fragments of the corresponding nucleic acid sequences could be employed.

Therefore, it is asserted that the specification does, in fact, provide adequate written description and enablement for the claimed invention. Accordingly, reconsideration and withdrawal of the Section 112, first paragraph, rejections are requested.

V. THE REJECTIONS UNDER 35 U.S.C. §102 ARE OVERCOME

Claims 19-24 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Safford et al. and Visser et al. The rejection is traversed. The claims are not, as stated by the Office Action, drawn to a composition comprising a single nucleic acid which inhibits

expression or activity of either GBSSI or BEI. Rather, the claims are drawn to the simultaneous inhibition of GBSSI and BE. Neither Safford et al. nor Visser et al. disclose the inhibition of both enzymes. Therefore, the subject matter of the claimed invention is not anticipated by these references.

Claims 1-6, 8, 10, 12-16, 19-24 and 29 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Flipse et al. This rejection is also traversed. The mutation of the GBSSI gene contained in the *amf* plants was generated by chemical mutagenesis, while the mutation described in the present application was generated by molecular biological techniques (antisense, cosuppression etc.). Therefore, genetic information of the plant cells according to the invention differs fundamentally from plant cells which have been chemically mutagenized.

Reconsideration and withdrawal of the Section 102 rejections are requested.

VI. THE REJECTIONS UNDER 35 U.S.C. §103 ARE OVERCOME

Claims 1-24 and 29 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Ek et al. taken with Visser et al. and Safford et al. in view of Kossmann et al. The rejection is traversed, as none of the cited prior art documents, even in combination with one another, discloses that modified waxy starches can be provided by simultaneously inhibiting the gene expression of GBSSI and BE genes. The waxy starch of the invention exhibits an increased phosphate content compared with waxy starches from plants which have a mutation only in the GBSSI gene. The increase in phosphate content also leads to a decrease in the gelatinization temperature (see page 14, lines 3-5 and 20-24 of the specification) of the starch of the instant invention. These results are surprising could not have been obvious.

The combination of the four cited references would not lead the skilled artisan to the instant invention. There are no teachings or suggestions in the documents which could predict the outcome of inhibiting both GBSSI and BE. Thus, the invention is not obvious and withdrawal of the Section 103 rejection is solicited.

CONCLUSION

In view of the remarks and amendments herewith, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

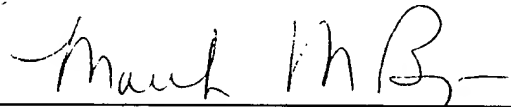
The Examiner is thanked for the acknowledgement of Applicant's priority claim under 35 U.S.C. Section 119, and for the acknowledgement of receipt of the certified copies of the priority documents.

No fee is believed to be due for entry and consideration of this paper. However, the Commissioner is hereby authorized to charge any required fees or to credit any overpayment in fees to Deposit Account No. 50-0320.

Respectfully submitted,

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By:

A handwritten signature in cursive script, appearing to read "Marilyn M. Brogan", written over a horizontal line.

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims:

1. (Amended) A transgenic plant cell which is genetically modified, the genetic modification leading to a decrease in the activity of one or more granule-bound starch synthase I (GBSSI) proteins occurring endogenously in the plant cell and to a decrease in the activity of one or more branching enzyme (BE) proteins occurring endogenously in the plant cell, in comparison to corresponding non genetically modified plant cells of wild-type plants.
2. (Amended) The transgenic plant cell as claimed in claim 1, the genetic modification comprising[consisting in] the introduction of one or more foreign nucleic acid molecules, wherein the[whose] presence and/or expression of the one or more nucleic acid molecules leads to a decrease in the activity of at least one GBSSI protein and at least one BE protein[s], in comparison to corresponding non genetically modified plant cells of wild-type plants.
3. (Amended) The transgenic plant cell as claimed in claim 1, wherein[in which] the presence and/or the expression of one or more foreign nucleic acid molecules leads to the inhibition of the expression of endogenous genes which encode at least one GBSSI protein and at least one BE protein[s].
4. (Amended) The transgenic plant cell[s] as claimed in claim 2, in which said foreign nucleic acid molecules are selected from the group consisting of
 - a) DNA molecules which encode at least one antisense RNA which brings about a decrease in the expression of endogenous genes encoding GBSSI and/or BE proteins;
 - b) DNA molecules which lead, via a cosuppression effect, to a decrease in the expression of endogenous genes encoding GBSSI and/or BE proteins;
 - c) DNA molecules which encode at least one ribozyme which specifically cleaves transcripts of endogenous genes encoding GBSSI and/or BE proteins; and
 - d) nucleic acid molecules, introduced by means of in-vivo mutagenesis, which lead to a mutation or insertion of a heterologous sequence in endogenous genes encoding GBSSI and/or BE protein, the mutation or insertion bringing

about a decrease in the expression of GBSSI and/or BE genes or the synthesis of inactive GBSSI and/or BE proteins.

8. (Amended) A process for the production of a transgenic plant cell which synthesizes a modified starch, in which a plant cell is genetically modified by the introduction of one or more foreign nucleic acid molecules, wherein the[whose] presence and/or expression of the one or more foreign nucleic acid molecules [lead/]leads to a decrease in the activity of at least one GBSSI protein[s] and to a decrease in the activity of at least one BE protein[s].

9. (Amended) A process for the production of a transgenic plant cell whose starch has an amylopectin content of at least 90% and an increased phosphate content in comparison to starch from corresponding plants of the waxy phenotype, in which a plant cell is genetically modified by the introduction of one or more foreign nucleic acid molecules, wherein the[whose] presence and/or expression of the one or more foreign nucleic acid molecules [lead/]leads to a decrease in the activity of at least one GBSSI protein[s] and to a decrease in the activity of at least one BE protein[s].

10. (Amended) A process for the production of a transgenic plant which synthesizes a modified starch, in which

a) a plant cell is genetically modified by the introduction of one or more foreign nucleic acid molecules wherein the[whose] presence and/or expression of the one or more foreign nucleic acid molecules [lead/]leads to a decrease in the activity of at least one GBSSI protein[s] and to a decrease in the activity of at least one BE protein[s];

b) a plant is regenerated from the cell produced according to step a); and,

c) if appropriate, further plants are produced from the plants produced according to step b).

11. (Amended) A process for the production of a transgenic plant whose starch has an amylopectin content of at least 90% and an increased phosphate content in comparison to starch from corresponding plants of the waxy phenotype, in which

a) a plant cell is genetically modified by the introduction of one or more foreign nucleic acid molecules, wherein the[whose] presence and/or expression of the one or more foreign nucleic acid molecules [lead/]leads to a decrease in the

activity of at least one GBSSI protein[s] and to a decrease in the activity of at least one BE protein[s];

- b) a plant is regenerated from the cell produced according to step a); and,
- c) if appropriate, further plants are produced from the plants produced according to step b).

15. (Amended) [The r]Reproductive material of a plant[s] as claimed in claim 12, containing plant cells as claimed in claim 1.

19. (Amended) A composition containing at least one of the nucleic acid molecules as defined in any one of claims 2 to 5 or 30 to 32[16 to 18], which is suitable for the production of transgenic plant cells as claimed in claim 1.

29. (Amended) A process for the production of a starch from a transgenic plant, plant cell, or plant reproductive material, wherein the transgenic plant, plant cell or plant reproductive material comprises genetic modification leading to a decrease in the activity of one or more GBSSI proteins occurring endogenously in the transgenic plant, plant cell or plant reproductive material and to a decrease in the activity of one or more BE proteins occurring endogenously in the transgenic plant, plant cell or plant reproductive material, in comparison to corresponding non genetically modified, wild-type plants, plant cells or plant reproductive material,[as claimed in claim 25] comprising extracting[the extraction of] the starch from the plant, plant cell or plant reproductive material [a cell as claimed in claim 1 or from a plant as claimed in claim 12 or from reproductive material as claimed in claim 15].